



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-1156]

#### Kenneth Zipperer: Final Debarment Order

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Kenneth Zipperer for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Zipperer was convicted of one felony count under Federal law relevant to these debarment proceedings for mail fraud. The factual basis supporting Mr. Zipperer's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Zipperer was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of March 30, 2022 (30 days after receipt of the notice), Mr. Zipperer had not responded. Mr. Zipperer's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

**DATES:** This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at <https://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Jaime Espinosa, Division of Enforcement (ELEM-4029), Office of Strategic Planning and Operational Policy, Office of Regulatory

Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at [debarments@fda.hhs.gov](mailto:debarments@fda.hhs.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On September 9, 2021, Mr. Zipperer was convicted, as defined in section 306(l)(1) of FD&C Act, in the U.S. District Court for the Western District of Wisconsin, when the court entered judgment against him for two offenses, one of which is relevant to these debarment proceedings: the offense of mail fraud, in violation of 18 U.S.C. 1341. FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: Mr. Zipperer acknowledged in his plea and sentencing hearing on September 9, 2021, that he owned and operated Zipperer Financial LLC where he worked as an insurance broker selling Medicare insurance policies to elderly individuals. Mr. Zipperer imported, via U.S. mail, foreign-sourced prescription drugs from an internet pharmacy company in India using the website "www.alldaychemist.com". The packages mailed from this pharmacy contained the return address of Derric Wood in Delhi, India, and Mr. Zipperer had these packages shipped to a P.O. Box he rented for Zipperer Financial LLC. Mr. Zipperer imported many of the foreign-sourced prescription drugs in wholesale quantities and broke down the bulk shipments and repackaged them into retail quantities for his individual clients. Mr. Zipperer distributed many of these foreign-sourced prescription medications to his clients in person, though he had no valid wholesale distribution license, pharmacy license, or license to prescribe prescription drugs.

Further, as Mr. Zipperer acknowledged in his plea and sentencing hearing on September 9, 2021, the prescription drugs Mr. Zipperer distributed to his clients were misbranded because they were foreign-sourced versions of various prescription drugs that were not approved by FDA for use in the United States and were dispensed to consumers without a valid prescription of a practitioner licensed by law to administer such drugs. The drugs were therefore misbranded because they did not contain adequate directions for use. Mr. Zipperer imported these misbranded prescription drugs in boxes containing customs declaration forms affixed outside the box that falsely declared that the contents were personal supply medications.

As a result of this conviction, FDA sent Mr. Zipperer, by certified mail, on February 14, 2022, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Zipperer's felony conviction for mail fraud, in violation of 18 U.S.C. 1341, was for conduct relating to the importation into the United States of any drug or controlled substance because he illegally imported misbranded prescription drugs and then distributed those drugs, unlawfully, to consumers. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Zipperer's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Zipperer of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Zipperer received the proposal and notice of opportunity for a hearing on February 28, 2022. Mr. Zipperer failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

## II. Findings And Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Kenneth Zipperer has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Zipperer is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see DATES). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug or controlled substance by, with the assistance of, or at the direction of Mr. Zipperer is a prohibited act.

Any application by Mr. Zipperer for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2021-N-1156 and sent to the Dockets Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at <https://www.regulations.gov> or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: July 18, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-15795 Filed: 7/22/2022 8:45 am; Publication Date: 7/25/2022]